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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,251	11/01/2001	Robert K. Naviaux	UCSD1140-1	9760

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/889,251

Applicant(s)

Naviaux

Examiner

Phyllis Spivack

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☐ Responsive to communication(s) filed on \_\_\_\_\_

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 1-27 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 1-27 is/are rejected.

7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

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The undersigned Examiner supports the goal of the Office to advance prosecution as expediently as is reasonably possible. Cooperation is requested with respect to the timely submission of any references deemed pertinent to the present application along with Form PTO-1449.

Claims 1-27 are presented.

Claims 1, 2-25 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

Claim 4 recites the limitation "carbonyl derivative of an amino acid". There is insufficient antecedent basis for this limitation in claims 1 and 2.

Claim 5 recites the limitation "carbonyl derivative of a dicarboxylic acid". There is insufficient antecedent basis for this limitation in claim 1.

The recitation in claim 1 and 25 "with substituents selected from the group consisting of H, C<sub>1-3</sub> alkyl, OH, NH<sub>2</sub> and halogen" lacks clarity. It is unclear whether the substitution relates to alkynyl, or alkyl and alkenyl as well.

The definitions for each group are preferably stated in an indented, subparagraph format. Clarification is required with respect to the R<sub>3</sub>, R<sub>4</sub> and R<sub>5</sub> terms. It appears each term may be hydrogen or optionally substituted alkyl, OH, NH<sub>2</sub> and halogen.

Claims 4 and 5 are rejected under 35 U.S.C. 112, both first and second paragraphs, as the claimed invention is not described in such full, clear, concise and exact terms as to enable any

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person skilled in the art to make and use the invention and for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention.

Applicant fails to particularly point out the definition of both "a carbonyl derivative of an amino acid" and "a carbonyl derivative of a dicarboxylic acid". The metes and bounds of the recitations cannot be precisely determined. Numerous compounds that lack enablement and an adequate teaching as to how to prepare them are encompassed in the claims. Undue experimentation would be required to embrace the scope of the claims. Applicant should recite those derivatives contemplated.

Claims 1, 3-25 and 27 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Definitions for the groups  $X_2$  and  $X_3$  within the definition of  $R_2$  in Formula I are critical or essential to the practice of the invention, but are not included in claims 1 and 25. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). One skilled in the art would be unable to prepare or to practice the claimed methods without a complete description of every term in Formula I.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Isono et al., JP 53056690 (abstract).

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Isono teaches the administration of N-acetyl, 2',3',5'-triacetate cytidine, a compound of instant Formula I, to treat angina, a symptom of a mitochondrial disorder, and to treat a hormone imbalance which may relate to a mitochondrial disorder.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

Claims 1-7 and 25-27 are rejected under 35 U.S.C. 102(e) as being anticipated by von Borstel et al., U.S. Patent No. 6,258,795.

Borstel teaches the administration of compounds of formula II and formula III to treat mitochondrial disorders or symptoms associated with mitochondrial disorders. See, in particular, column 10, lines 26-60.

No claim is allowed.

Any inquiry concerning this communication should be directed to Phyllis Spivack at telephone number (703) 308-4703.

April 12, 2002

*Phyllis Spivack*

PHYLLIS SPIVACK  
PATENT EXAMINER  
GROUP ~~128~~ 1614